

## REMARKS

Claims 1-22 remain pending in this application with claims 17-22 withdrawn from consideration. Claims 1-3, 8, and 9 have been amended by way of this amendment. The specification also has been amended to show the corresponding patent number for Serial No. 09/259,705. The amendment is believed not to introduce new matter.

Reconsideration and withdrawal of the rejections is requested in view of the following remarks.

### Pyka, et al.

Claims 1, 6 and 7 were rejected under 35 U.S.C. §102(b) as being anticipated by Pyka, et al. (US 5,002,563). Claim 1 as amended describes a method of holding valve leaflets in a patient together where a clip is placed across the two valve leaflets. Pyka, et al. merely describes a suture for suturing a wound and is devoid of any disclosure or suggestion of using the suture to hold relatively thin tissue together in a surgical valve repair procedure.

Pyka, et al. involves a suture that is constructed to overcome problems associated with devices used to close “deep tissue wounds.” Pyka, et al. notes that staples and bands generally provide only surface closing of the wound and that only sutures provide the important capability of holding together deep tissue wounds. However, since the sutures may provide an undesirable shear force that may interfere with proper alignment of the wound edges, multiple layers of sutures, which are difficult place, are necessary (col. 2, lines 25-68). Thus, the Pyka, et al. wound closure suture mechanism is constructed to close “deep tissue wounds.” There is no disclosure or motivation in Pyka, et al. to use the shape memory sutures 10, which are constructed for deep wound closure, to hold relatively thin tissue together, let alone to hold valve leaflets together.



Pyka, et al. in view of Northrup, III, et al. and Ebert

Claims 2 and 8 were rejected under 35 U.S.C. §103(a) as being unpatentable over Pyka, et al. in view of Northrup, III, et al. (US 5,972,024) and Ebert (US 5,127,413). The Examiner advanced that it would have been obvious to add a flexible member to the Pyka, et al. shape memory suture and to detachably attach that flexible member to the Pyka, et al. shape memory suture in view of the flexible member that is secured to the clip in Northrup, III, et al.

First, Pyka, et al. does not disclose or suggest using the Pyka, et al. device to hold valve leaflets together and there is no suggestion in the secondary references to use or modify the Pyka, et al. deep wound closure suture for holding valve leaflets together.

Applicant also submits that the advanced combination of Pyka, et al. and Northrup, III, et al. is improper. A rejection based on obviousness requires there to be motivation to carry out the proposed modification. Specifically, the references relied on must provide a reason or incentive to carry out the modification and there must be some reasonable expectation of success. Both of these elements are missing. There is no suggestion in Northrup, III, et al. to add a suture (20) to the Pyka, et al. suture (10). Further, there is no explanation as to how the additional suture (20) would be incorporated to avoid premature closing of the Pyka, et al. self-closing suture during delivery. Although Northrup, III, et al. may describe advantages of combining a suture with a holding device as disclosed therein, Northrup, III, does not suggest combining a suture with the self-closing holding device of Pyka, et al., which already has a delivery mechanism. If the Examiner believes motivation to carry out the suggested modification is present, Applicant requests that the Examiner show where that motivation, including suggestion as to how the modification would be carried out, is founded in the references.

Further, and with regard to claim 2, none of the references disclose or suggest using two flexible members and two needles.

Regarding claim 8 as amended, not only do the references lack the requisite motivation to add a flexible member to Pyka, et al. as set forth above, there is no suggestion in the references to use a clip that is “detachably attached” to a flexible member. Specifically, There is no suggestion of modifying the Pyka, et al. device to include a flexible member that is “detachably attached” to

Pyka, et al.'s suture (10). The suture in Northrup, III, et al. is connected to the holding device 60, for example, by swaging (col. 4, lines 9-12). After the holding device is, for example, crimped into a holding configuration, a tool can be used to separate the suture from the holding device, for example, by cutting (col. 4, lines 61-65). If the flexible member were "detachably attached" to the holding device, such cutting would not be required. Accordingly, Northrup, III, et al. does not suggest modifying Pyka, et al. to use a clip that is detachably attached to a flexible member.

Pyka, et al. in view of Northrup, III, et al., Ebert and Hasson

Claims 3-5 and 9-16 were rejected under 35 U.S.C. §103(a) as being unpatentable over the combination of Pyka, et al. in view of Northrup, III, et al. and Ebert and further in view of Hasson (5,628,757).

The foregoing arguments that the references lack the requisite motivation to add a flexible member to Pyka, et al. apply with equal force to the rejection of claims 3-5 and 9 (as amended) - 16.

In further regard to claims 3-5, the arguments made with respect to claim 2 equally apply.

Applicant also submits that the rejection is based on improper impermissible hindsight application of the teachings of Applicant's disclosure. For example, no reason has been established to insert the Pyka, et al. sheath 32 through a "cannula" (claim 3). Nor is there any motivation to use the outer tube and inner member combination of claim 4 or the spring as set forth in claim 5.

In further regard to claims 9-16, there is nothing in the references that provides incentive to one of skill to modify the Pyka, et al. device to further include "a needle holder including an outer tube and an inner member which has a front end adapted to grab the needle and is slidable inside said outer tube."

Pyka's Figure 3 illustrates an embodiment where a stiff sleeve 32 serves to retain the suture 10 in a relatively longitudinally extending shape. The sleeve can be used to directly drive the needle 14 through the tissue and it also can have a sharpened distal end to push the suture member 18 through the tissue (col. 6, lines 7-14). There is no suggestion as to why one would place another member in sleeve 32, which member is adapted to grab the needle, let alone how

one would do it.

The rejection appears to be nothing more than improper impermissible hindsight application of the teachings of Applicant's invention. It is well settled that the motivation to carry out a modification must be founded in the applied references and not in Applicant's disclosure.

Although the dependent claims allowable for depending upon allowable claim 9, they are allowable for containing allowable subject matter as well. For example, the references do not disclose or suggest the needle and flexible member pair of claim 10, the spring as set forth in claim 11, or the slit of claims 12 and 13.

If the Examiner maintains any of the foregoing rejections, Applicant requests that the Examiner clearly point to specific examples in the cited references that support any rejection so maintained. If a telephone interview would advance prosecution of the application, the Examiner is invited to telephone the undersigned at the number provided below.

## CONCLUSION

The undersigned believes that all claims now pending in this application are in condition for allowance and respectfully requests the issuance of a formal Notice of Allowance at an early date.

In the unlikely event that the transmittal letter is separated from this document and/or the Patent Office determines that an extension and/or other relief is required, Applicant petitions for any required relief including extensions of time and authorizes the Assistant Commissioner to charge the cost of such petitions and/or other fees due, including additional claims fees, in connection with the filing of this document to Deposit Account No. 50-1947 referencing Attorney Docket No. CSI-2013.

Respectfully submitted,

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